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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,556	11/21/2001	Charles William Rowe	900122.437	3514

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	8

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/991,556	ROWE ET AL.	
	Examiner	Art Unit	
	Susan Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *11-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Declaration, Fee, and Power of Attorney filed 02/11/02, Information Disclosure Statement filed 03/29/02, and Response to Restriction Requirement filed 04/10/03.

Election/Restrictions

Claims 11-53 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Applicant's arguments filed 04/10/03 have been fully considered but they are not persuasive.

Applicant's election with traverse of group I, claims 1-10 invention in Paper No. 7 is acknowledged.

Requirement for restriction practice are set forth in MPEP§803.

There are two criteria for a proper requirement for restriction between patentable distinct inventions:

1. The inventions must be distinct as claimed (see MPEP§806.05-806.05(i)); and

2. There must be a serious burden on the examiner if restriction is not required (see MPEP§803.02, 806.04(a)-(j), 808.01(a) and 808.02).

The traversal is on the ground that all of the solicited claims must be examined on the merits because the examination of all claims would not constitute a serious

burden. This is not found persuasive because method and product claims are statutorily distinct categories of invention, and the particular method claimed is distinct from the particular product claimed because there is an alternative method of making the product. Therefore, there is no reason why a search for the method must include a search for the product as well. The existence of an alternative method of making the product, as well as the different classification of five inventions, provide evidence of a burden on the examiner in examining both inventions.

Distinctness between a process of making and the product made is shown if "the product as claimed can be made by another materially different process." MPEP§806.05(f). In the restriction requirement, the examiner set forth several "materially different processes" by which the claimed product could be made.

A serious burden on the examiner is shown according to the criteria of MPEP§808.02, where one of the following must be supported by appropriate explanation:

1. Separate classification thereof:

This shows that each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search,. Patents need not be cited to show separate classification;

2. A separate status in the art when they are classifiable together; and

3. A different field of search.

In the restriction requirement dated 03/10/03, the examiner set forth separate classification for the five inventions to which claims were presented. Applicant has not

alleged that either product or process claims were improperly classified. Nor has applicant alleged that the classifications set forth are not "separate classifications." Thus, requirement 2 of MPEP§803 is met. For these reasons set forth above, the restriction requirement is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "wherein the method is" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 is a product claim, the method that claim 2 refers to has not been introduced in claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Cima et al. US 5,490,962.

Cima teaches a porous matrix device for controlled release of bioactive agent prepared by solid free form fabrication methods, including three dimensional printing (see abstract, columns 2-4, 7-10, and examples 2-3).

Claims 1-4, 6-8, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Payumo et al. US 2002/0015728 A1.

Payumo teaches an oral dosage form, such as porous matrix containing drug or combination of drugs (see abstract, page 3, and example 1). The dosage form is prepared by solid free form fabrication method with three dimensional printing device (page 2). Payumo further teaches that the drug is in an amorphous form (page 4, paragraph 0039). The dosage form further comprises surfactant, and steric hindrants, *e.g.*, polyvinyl pyrrolidone (page 4, paragraph 0040, and example 1). Payumo also teaches the oral dosage form having average particle size of about 0.5 μm (example 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Payumo et al. US 2002/0015728 A1.

Payumo is relied upon for the reason stated above. Payumo does not teach the viscosity value of the suspension as claimed in claim 5. However, Payumo teaches the use of gel-forming polymer in the suspension to prevent the binder liquid to spread further after it has interacted with the substance (pages 4-5). Accordingly, such language suggests that the suspension of Payumo is viscous. Thus, it would have been obvious for one of ordinary skill in this art to, by routine experimentation determine a suitable viscosity value to obtain the claimed invention, because Payumo teaches the advantageous results in the use of similar materials and method to prepare a dosage form desired by the applicant, namely, an oral dosage forms prepared by suspension printing or three dimensional printing with pharmaceutical drugs.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Payumo et al. US 2002/0015728 A1, in view of Monkhouse et al. US 6,280,771 B1.

Payumo is relied upon for the reasons stated above. Payumo is silent as to the teaching of the drugs claimed in claim 9.

Monkhouse teaches a porous matrix device for controlled release of bioactive agent prepared by solid free form fabrication methods, including three dimensional printing (see abstract, and columns 7-8). The bioactive agent including pharmaceutical

drugs, *e.g.*, nitrofurantoin (example 4). Thus, it would have been obvious for one of ordinary skill in the art to optimize Payumo's oral dosage form using nitrofurantoin as a pharmaceutical drug to be incorporated into the matrix in view of the teachings of Monkhouse, because the references teach the advantageous results in the use of oral dosage form prepared by solid free from fabrication using three dimensional printing techniques.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sachs et al., Yoo et al., and Shastri et al. are cited as being of interest for the teachings of three dimensional printing techniques to prepare a pharmaceutical dosage form.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600